Patient Monitor Manual
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Section 1 *Preface*

Your accepting of our production is greatly appreciate,
and it is important before you turning on the monitor that we recommend you strongly to read the **security clauses and cautions clauses**.

Please **pay attention** to the clause where **marked ●**

§1.1 Working Environment

This patient monitor can work in following environment：

- Temperature: 10℃～40℃
- Relative Humidity: 30%～75%
- Atmospheric Pressure: 70kPa～106kPa
- Build-in Battery: Li battery 7.4V 2.2A
- Input Power: 15VA
- Adapter Input Power: AC220V±22V 50Hz

§1.2 Security

- Keep the equipment off the flammable gas and oxygen pot, Otherwise some undesirable results may come out such as exploding.
- Avoid using the equipment in the circumstances such as strong magnetic field, coagulable environment, too many dust surroundings and shaking condition.
- Do not put the equipment in the circumstances where may be sprinkled by water or too wet atmosphere.
- If the equipment is sprinkled by liquid, it is imperative that cut off the power immediately and check out the equipment to make sure it is not damaged.
- Make sure the electrodes and temperature probe is insulated with other conductor and earth.
- It is noteworthy that some other equipments may cause disturbance and the disturbance could influence the security of the patient through the electrode leads when heart-pacemaker is inspected.

§1.3 Notice

- Avoid any collision to the equipment because the LCD screen may be heavy damaged.
- Avoid curving the electrode leads or probes in an acute angle or pressing them by rigid material or dragging them .All the action above may cause the electrode leads or probes inside broken or desquamation.

ECG Monitoring(All the situation followed may disturb the measure)

- Make sure the disposable Ag/Agci snap-on skin electrodes are adopted when the equipment work in the same time with de-trembling. Using other electrode may cause negative influence to the ECG waveform and slow down the baseline reset, even cumber some of the monitoring function after using de-trembling.
- When work with electrosurgical unit, please position the equipment as section §4.1.4 described. Otherwise the electrosurgical unit may produce disturbance and disorder ECG monitoring, causing inaccurate analysis and arrhythmia report.
- In the situation when the ECG signal is overflow or the electrode lead break off, the equipment will show“electrode lead break off”, at the moment the ECG data displayed is already inaccurate.
- When patient with heart- pacemaker is monitored, asynchronous signal may cause inaccurate ECG data.

SpO2 Monitoring(All the situation followed may disturb the measure)

- When the patient is in the situation of shock or cardiac muscle anabiosis, the SpO2 measure may be inaccurate because of movement of the patient.
- The data may be inaccurate when HbCo MetHb raise abnormally.
- The data may be inaccurate when the equipment works with electrosurgical unit.
- The data may be inaccurate when the blood is mixed with pigmented material.
- The data may be inaccurate when the pulse waveform is too feeble.
- The data may be inaccurate when the probe is damaged.

NIBP Monitoring

- In case of timing interval NIBP Monitoring or consecutive NIBP Monitoring, please check the hands ,feet and blood vessel of the patient and make sure the circulation of blood is in good condition.

Section 2 *General*

§2.1 Usage

Patient monitor is competent for the monitoring of the Echocardiograph, Heart Rate, Temperature, Blood pressure, Respiration and SpO2.

§2.2 General Information

This equipment include Main Unit, Electrode Lead, Blood pressure NIBP cuff, SpO2 Probe, Temperature Probe etc.

This equipment is I Class CF Normal Unit, it can resist the disturbance of High Frequency E-knife.

This equipment accord with Chinese National Criterion GB9706.25 and GB9706.1.

§2.3 Accessories

When you open the package of patient monitor, besides the main unit, you can find some accessories as follow:

□ 1 Copy of Patient Monitor Manual

□ An Accessories Package which contains accessories as follow:

§ 1 set of 5 Electrodes Lead

§ 1 set of Blood pressure NIBP cuff used for adult

§ 1 set of SpO2 Probe

§ 1 set of Temperature Probe with a range of 0～50℃

§ 1 of 12V/2A AC Adapter

§ 30 sets of Attaching Disposable Electrode

§ 1 set of portable printer(If optional module Printer selected)

§ 1 set of printer connection cable(If optional module Printer selected)

§ 1 roll of printer paper(If optional module Printer selected)

- All the accessories should use the original accessories from our company, otherwise the performance of the monitor may be reduced.

Classification of the Accessories:

Classification	Description	Specification	Remark
Bloodpressure NIBP cuff	For Baby	Width:8cm	All the Blood pressure NIBP cuff should be replaced after one year operation.
	For Child	Width:10cm	
	For Adult	Width:15cm	
	Windpipe	Length:2m	
SpO2 Probe	Type BCI	Length:2.5m	The Probe should be replaced after one year usage or more than 6000 hours operation.
Temperature Probe	Heat-Sensibility Resistance	Length:2m	
Electrode Lead	CNT04	Length:3m	
Adapter	AC Adapter	12V/2A	
Battery	Li battery	7.4V 2.2 A	The battery should be replaced after one year operation or more than 200 periods of recharge.
Printer (Optional)	Portable Printer		
Printer connection cable	With the printer	Length:1m	

Table 2

Classification of Consume Material

Name	Description	Manufacturer	Remark
Attaching Disposable Electrode	Ag/Agci	LiTu medical equipment Co.,Ltd ShangHai	Could work with de-trembling
Heat-sensitived Print Paper	Φ50*20m	Medical printer paper Co.,Ltd TianJin	White colour

Table 3

Specification of Attaching Disposable Electrode:

AC resistance ≤3KΩ

De-trembling abnormal voltage ≤100mV

Simulated de-trembling reset capability:

5 sec alt spark voltage between probes≤100mV

Average change rate in 10 sec ≤1mv/s

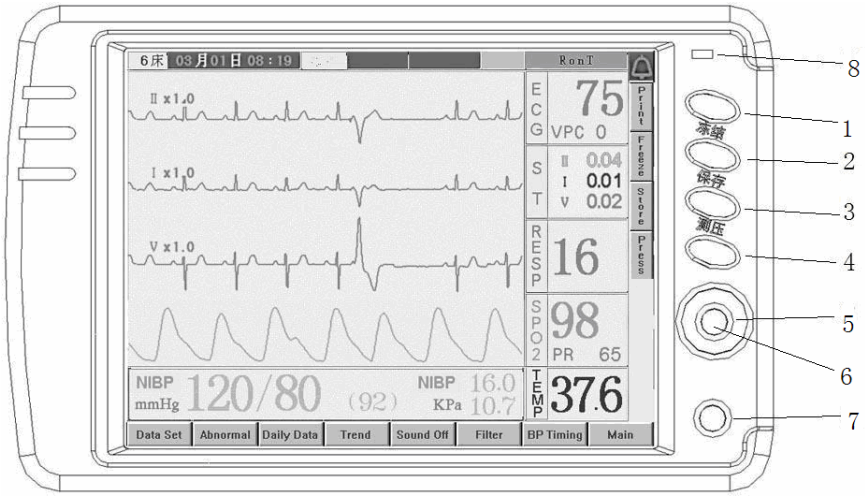
AC resistance after simulated de-trembling ≤3KΩ

Bias current allowance ≤100mV

Section 3 Setup

§3.1 Operation Instructions of Setup

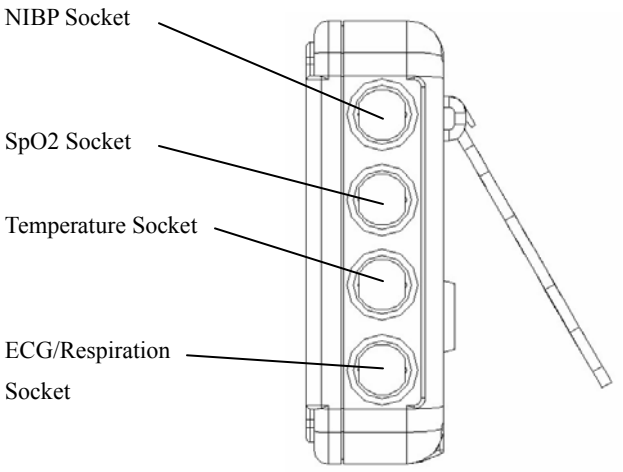
§3.1.1 Instructions of Front Panel



Pic 1

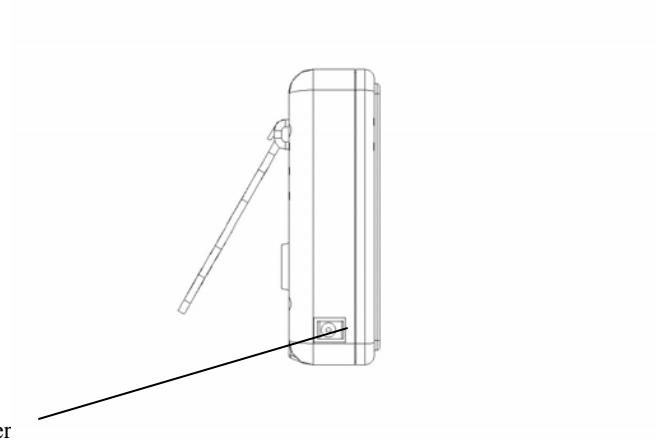
1. PRINT Waveform is printed after pressing this key.
2. FREEZE Waveform is frozen after pressing this key.
   Pressing again free the frozen waveform.
3. STORE Waveform is stored on the screen after pressing this key.
4. PRESS Blood pressure is measured manually after pressing this key.
   Pressing again stops this measurement.
5. Four-Direction Key Pressing four-direction key to move the cursor to the menu.
6. Confirm Key Pressing the medial key of the four-direction key to confirm the selection.
7. Power Key Pressing this key to On/Off the monitor.
8. Indicator Ligh Indicate the state of power supply.

§3.1.2 Instructions of Right Side Panel



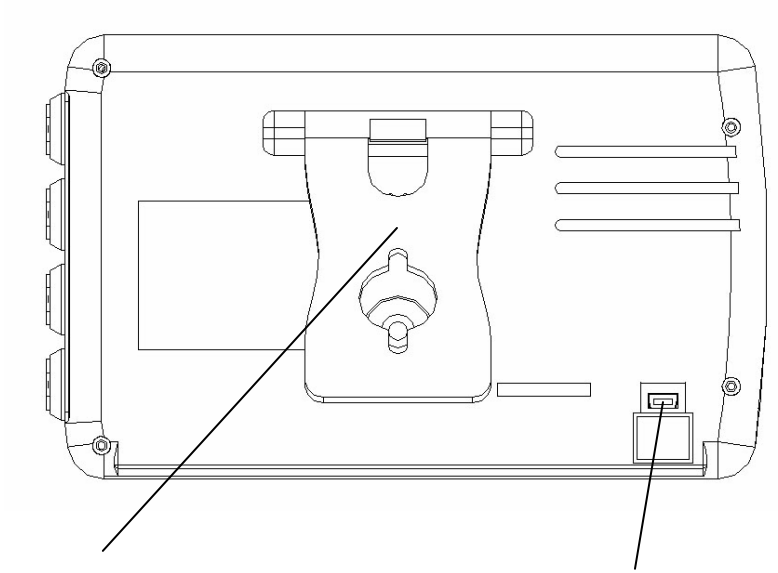
Pic 2-A

§3.1.3 Instructions of Left Side Panel:



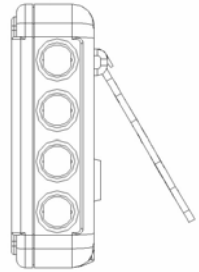
Pic 2-B

§3.1.4 Instructions of Back Side Panel



The transformation shelf in the back of the monitor is designed for setting of the position of shelves and hanging.

In the position of shelves, operator can rotate the shelf to 30 degree and the shelf is automaticly fixed. As Pic 3-A shows.



Pic 3-A

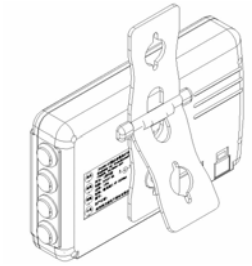
In the position of hanging, operator can operate as follow:

Step1 Rotate the shelf to 135 degree.

Step2 Push the shelf and rotate the shelf to 180 degree. Then the shelf is in the

position of hanging. As Pic 3-B shows.

Step3 Push the shelf again operator can rotate the shelf to other position.

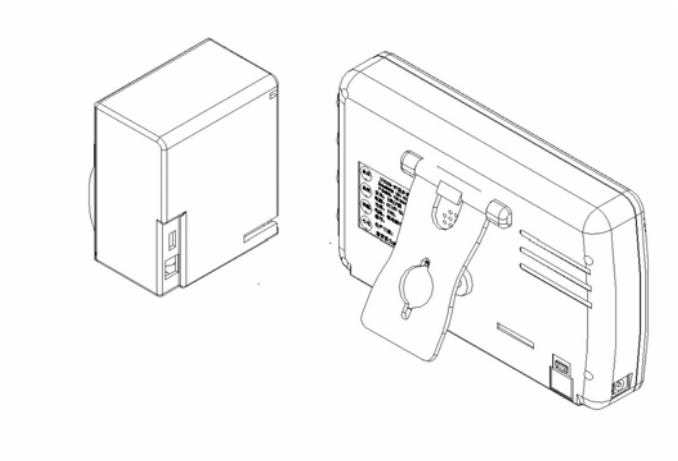


Pic3-B

On the Back Side Panel, there are also some appendent interface sockets used for some client with specific demand, so most of the client do not need and may not use these interface sockets self-determinedly.

§3.1.5 On-line Printer(Optional)

can work with portable printer with the connection cable:



Pic 4-A

The processing of setup printer paper is as follow:

(A) (B) (C)

Pic 4-B

A. Following the direction of the arrowhead, move the wedged bulge to unlock the cover of the box of Printer Paper.

See the details in Pic No.4-B-(A)

B. Following the Picture, position 1 roll of the Print Paper in the box. Please be cautions that the heat-sensitived side of the Print Paper must face to up.

See the details in Pic No.4-B-(B)

C. Pull several centimeters of the Print Paper, then close the box. Please notice the lock of the box and make sure it is locked.

See the details in Pic No.4-B-(C)

Specification of the Print Paper is 50mm×20m. The heat-sensitived side must face to the inside of the box.

Please clean the surface of the nozzle of the Printer before changing the Printer Paper. The width of the Print Paper should not wider than the sawtooth of the printer.

§3.1.6 Power

The Power or de-trembling Power from the battery is applicable to the equipment.

The equipment will use AC Power first, the battery in the equipment can be recharged automatically.

When the battery with enough power, the battery will work automatically when the AC Power cut off. This course has no influence to the measure.

The battery can only be recharged by this equipment, and do not cut off the Power

during the course of recharging. The whole course of recharging will cost approximately 8 hours. Before the situation of storing the battery or first using the battery, please recharge the battery to the full state, and after more than 1 month of storing, please recharge the battery again before using it.

The process of disposing battery: If the battery can only hold less than 0.5 hours, please replace it. The used battery should be disposed appropriately according to the rule of some relevant law.

§3.1.7 Necessary preparations before monitoring

A. If the battery is needed, please check if the power of the battery is full.
B. The key and the switch is in good condition.
C. The environment of the equipment is dry.
D. The Power cord and all kinds of probes are in good condition.

§3.1.8 Necessary back-check after monitoring

A. Some settings for temporary situation should be changed to the ordinary setting.
B. The Probe and other accessories should be cleaned, disinfected and well stored.
C. Clean the dirt on the equipment.
D. The battery is in full state.
E. After turn off the equipment, please cut off the connection of Power.
F. The equipment should be stored in the dry environment.

§3.2 Turn On the Monitor

After turning on the monitor, please check the indicator light which means different state of the equipment.

Green Colour Retaining: Using Power

Orange Colour Retaining: Using battery power

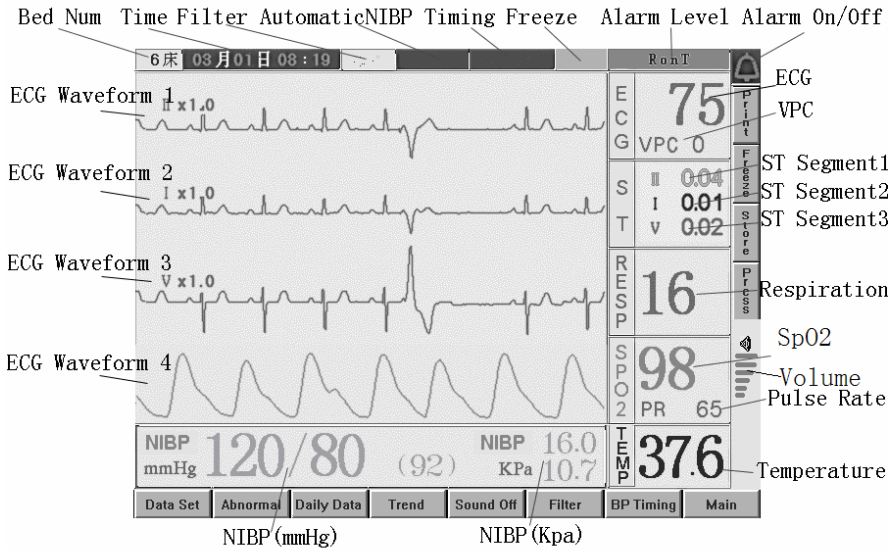
Orange Colour Glittering: Recharging the battery

Red Colour Glittering: Low power in the battery

- If the indicator light do not work, please check if the Adapter is connected appropriately.

- If there is any other trouble, please cope with it following “Section7 Error Messages and Troubleshooting”.

The initial displayed information showed on the screen is in Pic No.5



Pic 5

Window of Alarm: red colour shows alarm, shows dismiss alarm.

Window of ECG: Shows the Heart Rate and VPC.

Window of ST: Shows the real time ST-Segment measurement.

Window of NIBP: Shows the Blood pressure(SYS/DIA and MEAN) in two forms(Kpa and mmHg).

Window of SpO2: Shows the SpO2 and Pulse Rate.

Window of RESP: Shows the rate of respiration.

Window of TEMP: Shows the measurement of temperature.

The functions of menus such as Data Setting, Abnormal Information, Daily Information, Trend Information, Alarm Function, Filters Function, Timing interval NIBP Monitoring and Help showed in the bottom of the screen will be instructed in “Section 5 Operation Instructions”.

Section 4 *Monitoring Functions Instructions*

§4.1 ECG Monitoring

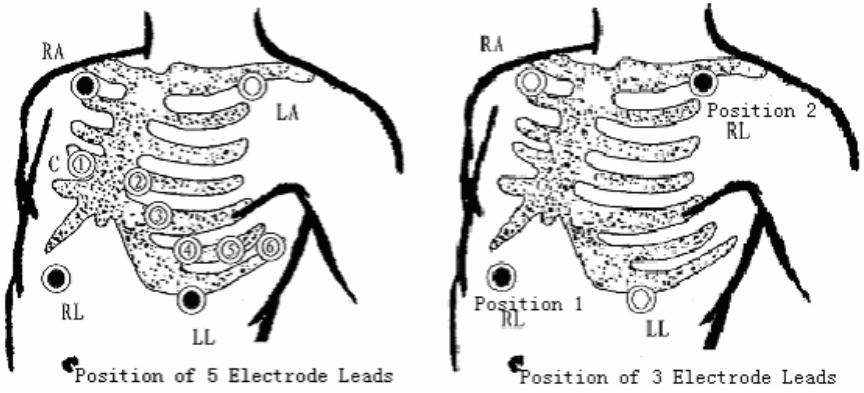
§4.1.1 Selection of Electrode Lead

The common method to monitor ECG is using 5 Electrodes Lead, which can obtain 7 Lead signals. The analogous Electrode Lead imitating the person Electrode Lead has the following signals: Standard Electrode Lead(Ⅰ, Ⅱ, Ⅲ), limbs Electrode Lead(aVR, aVL, aVF) and bosom Electrode Lead(V). There is slight difference of the waveform of ECG between bosom Electrode Lead and limbs Electrode Lead. The main difference is the amplitude of the ECG waveform. Changing the position of the Electrode Lead or adopting the method of limbs Electrode Lead can get more desirable waveform. You can also put the Electrode Lead as following table if you want to get one Lead waveform specially.

Definition of the Electrode Lead

Mark of Electrode Lead (Europe)	Mark of Electrode Lead (International)	Position of Mark Ⅰ and aVR	Position of MarkⅢ and aVF
L A(Yellow)	LA (Black)	Left anterior axillary line	Left supraclavicular fossa
R A(Red)	RA (White)	Right anterior axillary line	Right anterior axillary line
LL(Green)	LL (Red)	Space between seventh and eighth rib on the left anterior axillary line	Space between seventh and eighth rib on the left anterior axillary line
C1 (White)	V1 (Brown)	Fourth intercostal space on the fringe of the right breastbone	Fourth intercostal space on the fringe of the right breastbone
C2 (White)	V2 (Brown)	Fourth intercostal space on the fringe of the left	Fourth intercostal space on the fringe of the left

		breastbone	breastbone
C3(White)	V3 (Brown)	Midpoint of the line between V2 and V4	Midpoint of the line between V2 and V4
C4 (White)	V4 (Brown)	Fifth intercostal space on the left mide-tremblinglavicular line	Fifth intercostal space on the left mide-tremblinglavicular line
C5 (White)	V5 (Brown)	Space between left anterior axillary line and fifth rib	Space between left anterior axillary line and fifth rib
C6 (White)	V6 (Brown)	Fifth intercostal space on the left mide-tremblinglavicular line	Fifth intercostal space on the left mide-tremblinglavicular line
RL (Black)	RL (Green)	Above the right side of the abdomen	Above the right side of the abdomen



Pic 6

Three Electrode Lead is used in operating room, but the result of Respiration monitoring could be inaccurate. The Electrode Lead can also be moved to the back side or the buttocks when the position of the Electrode Lead would be in operating.

§4.1.2 Position the Electrode Lead

The measure of ECG adopts Attaching Disposable Electrode, the position of the electrode would influence the signal of the ECG. Before the electrode is put in right position, please keep the skin as clean as necessary. The step is as following:

A. Use the rubber rub the skin softly.

B. If the patient is lipid-skin, please use alcohol to rub the skin first, after the alcohol is evaporated, then execute step A.

C. Please warm the position where put the electrode by warm towel in the winter, then execute step A.

D. Connect the electrode lead and the electrode.

E. Uncover the insulation paper on the electrode from the edge.

F. Stick the stickiness side of the electrode to the skin where be rubbed firmly.

G. Do not stick the electrode to the skin where is not flat.

H. If the wave of ECG is disturbed, please check whether the stickiness side of the electrode is still stickiness or the electrode exceed the time limit.

§4.1.3 Selection of ECG Wave

This equipment uses the No.1 Lead waveform from the Ⅱ Electrode Lead to monitor to display ECG signal. So the first Lead is set to Ⅱ Electrode Lead automatically when monitor the ECG. Other Lead can use to display other waveform form Electrode Leads. The No.4, No.5 and No.6 Lead can be set to display the waveform of Blood, SpO2 and Respiration. The detail setting step is shown on §5.1.4.

Please select the times of amplifying signal appropriately. The times of ECG signal amplifying is 0.5～3.0, you can set to 0.75～1.0 in normal situation. The detail setting step is shown on §5.1.5.

§4.1.4 Working with Electrosurgical Unit

This equipment can eliminate the disturbance of electrosurgical unit. It can recover to the normal state after 10 seconds when the High-Frequency disturbance and magnetic field is eliminated and the data stored is reserved completely.

Please possibly position the equipment far away from the electrosurgical unit when work with electrosurgical unit. Please put the equipment to the opposite side of the

operation table if it is possible.

Please insert the connector plugs of adapter to the different AC sockets when the equipment works with electrosurgical unit, and try to separate the two AC sockets as far as possible.

Please make sure the electrode is stick to the patient firmly when the equipment is working with electrosurgical unit. Otherwise, the improper connection will harm the skin of the patient.

Please use the three Electrode Leads measurement to avoid the disturbance.

Please protect the spare metal part and the temperature probe connected the equipment by some insulation method, and make sure the metal part and the temperature probe is insulated to other metal or ground. Otherwise the patient and the operator may be harmed by lightning.

§4.1.5 Work with de-trembling function

When work with de-trembling, the operator should not attach to the patient, the bed and the equipment connected to the patient to avoid to be injured.

§4.2 Respiration Monitoring

The electrode to monitor respiration and ECG is same. Please put the Black Electrode Lead(Marked N)in the position where the fluctuation of the abdomen is maximum to enhance the sensitivity of the measure. The rate of respiration is displayed on the screen, the data stored can be reviewed in Daily Information, and the wave of respiration can also be displayed on the screen.

The monitoring may be inaccurate due the patient's obesity, because the fluctuation of the abdomen is insensitive or there are only three Electrode Leads used to measure the respiration.

§4.3 NIBP Monitoring

The NIBP is measured from the change in amplitude pattern of pulsatile oscillation in NIBP cuff pressure as the NIBP cuff pressure is reduced from above systolic to below

diastolic pressure. The occlusive-oscillometry method uses this to determine the systolic, diastolic, and mean arterial pressure.

The systolic pressure is the pressure at which the pulsatile oscillation suddenly increases, and the diastolic pressure is the pressure at which the pulsatile oscillation suddenly decreases. The mean arterial pressure is the point where maximum pulsatile oscillation occur.

The measure of NIBP of this equipment adopt more advanced method which is one-step method. According to this method the precision of the measure can be enhanced and the measure time can be reduced to two thirds.

§4.3.1 Step of NIBP Monitoring

A. Connect the air hose to the socket of NIBP on the equipment.

Please make sure that the connection of the air hose and the socket is firm.(You can heard a sound of "Ka", if you insert the air hose correctly.) Otherwise, the NIBP cuff may not work properly, the leaking air may lead to incorrect data or the failure of measurement.

B. The position of the NIBP cuff is that the bottom of the NIBP cuff should above the elbow more than 1cm～2cm, and the sign of the NIBP cuff should be in the artery of the inside arm.

Please take off the overclothes and the sweater to make sure the accuracy of the NIBP measure.

C. The NIBP cuff should keep close to the arm and the interspace between them should not be more than one finger space.

Do not tight the NIBP cuff too tight or too loose. Too tight may cause the patient uncomfortable and lead the data measured low than the normal dare; too loose may cause longer measure time and lead the data measured high than the normal data.

Please keep the air hose away from patient and bed to avoid inaccurate measure.

The air hose should not be folded or twisted.

Please check the NIBP cuff and colligate it again every 8 hours to make sure the blood can flow fluently.

D. The patient's arm should lay on the table and palm face to up, the NIBP cuff should at the same level with heart, if the patient is in the situation of sitting.

Operator can revise the measured data as following method: If the NIBP cuff higher

than heart, the result of NIBP can add 2mmHg by each inch(or 0.1kPa each centimeter); if the NIBP cuff lower than heart, the result of NIBP can reduce 2mmHg by each inch(or 0.1kPa each centimeter).

The measured data could be influenced by some kinds of medicine. The result of NIBP may be inaccurate to the patient who is in the situation of hyperkinesia

§4.3.2 Manual NIBP Monitoring

Pressing key of "PRESS", manual measure NIBP would work on. The equipment can complete task of charging air, measuring blood pressure and exhausting. The time of measuring is about 15～40 seconds. All the process can be terminated by pressing key of "PRESS" again.

Time between two measurements should longer than 40 seconds to make sure the air in the NIBP cuff have been exhausted completely.

§4.3.3 Automatic NIBP Monitoring

Please set the interval of the two measurements(ranged 1minute to 240 minute) if in the mode of automatic NIBP Monitoring. The detail setting method is shown on §5.2.3.

Startup Automatic NIBP Monitoring: You can press the "BP AUTO" key on Front Panel or the "BP Timing" in the bottom of screen to startup Automatic NIBP Monitoring. Then, the message "BP Timing" and the countdown time will be displayed on the top of the screen. When the countdown time shows zero, the Automatic NIBP Monitoring will start automatically.

Stop Automatic NIBP Monitoring: You can press the "BP AUTO" key on Front Panel or the "BP Timing" in the bottom of screen again to terminate Automatic NIBP Monitoring.

Please check the function of automatic NIBP monitoring whether it is on or the automatic timing is zero, if the NIBP cuff is not colligated. Measuring with the not well colligated NIBP cuff will damage the monitor.

§4.4 SpO2 Monitoring

SpO2 is monitored by attaching a probe to the patient and using the SpO2 socket on the monitor.

§ 4.4.1 Step of SpO2 Monitoring

A. Connect the probe to the SpO2 Socket of the equipment.

Please confirm the SpO2 Probe is connected correctly and firmly(You can hear a sound of "Ka" if you connect correctly).

B. Wait for the red light twinkling several times(about several second). Then open the clamp-liked probe, clamp the forefinger. Please make sure the root segment of nail of forefinger is just facing the position of the clamp where is emitting the red light.(See in Pic No.7(A))

Other finger could be used to monitor SpO2 if the forefinger is unsuitable.

Please do not put SpO2 probe to the limb where is used for NIBP monitoring.

C. Please press the flank of the clamp-liked probe to make it attach to the patient firmly. The wire of the probe should follow the direction of arm. (See in Pic No.7(B))

D. The probe and wire can be wrapped by adhesive tape to reduce the disturbance.(See in Pic No.7(C))

Please check the skin clamped by the probe every 4 hours, and change other finger to monitor SpO2.

Measurement may be incorrect in the following case:

When the patient's carboxyhemoglobin or methemoglobin increases abnormally.

When using an electrosurgical unit.

When dye is injected in the blood.

When there is body movement.

When there is vibration.

When measuring at a side with venous pulse.

When the pulse wave is small(insufficient peripheral circulation).

When using an IABP(intra-aortic balloon pump)

In the situation of strong light, please cover the probe with a opaque paper or fabric to ensure the correct measurement.

(A) (B) (C)

Pic 7

§4.5 Heart/Pulse Rate Monitoring

Heart Rate monitoring is according to the waveform of ECG, and is displayed in the ECG window.

Pulse Rate monitored is according to the waveform of SpO2 measurement, and is displayed in the SpO2 window marked PR.

§4.6 ST-Segment

ST-Segment monitoring is displayed in the ST-Segment window with 3 Leads of ST-Segment measurement. The alarm of ST-segment is controlled according to the data measured in The No.1 Lead ECG waveform. The colours of the ECG Lead are corresponded to those showed in the ST-segment window.

§4.7 Temperature Monitoring

Temperature is monitored by attaching temperature probe to the skin of the patient. Please connect the probe to the temp socket on the equipment and wrap the probe by adhesive tape to make sure it attach the patient firmly.

The temperature measurement is displayed in the TEMP window.

Section 5 Operation Instructions

There are several menus on the menu showed in the bottom of screen and 4 keys on the front panel. Operator can use four-direction key and confirm key to enter each secondary menu and setup the detail setting.

The functions of menus are described as follow:

A. Data Setting(Showed Data Set for short in screen): Operator can modify the date setting, selection of waveform and colour showed in each Lead, times of amplifying, speed of scanning, automatic NIBP timing and alarm setting.

B. Abnormal Information(Showed Abnormal for short in screen): Operator can review the abnormal data waveform and record of ECG.

C. Daily Information(Showed Daily Data for short in screen): Operator can review the daily data by index.

D. Trend Information(Showed Trend for short in screen): Operator can check the data of ECG, NIBP, SpO2, Temperature and Respiration by chart.

E. Sound Off: Operator can start/terminate the function of alarm.

F. Filter: Operator can start/terminate the function of filter.

G. Automatic NIBP(Showed BP Timing for short in screen): Operator can start/terminate the function of automatic NIBP.

H. Help: Operator can read the E-document of helping stored in the equipment.

I. Volume: The volume menu on screen can control the volume. Operator can press four-direction key to move the cursor until the colour of "🔊" is changed(The Volume cursor is just on the right of BP-Timing cursor or on left of Help cursor). Then press confirm key entering the state of changing volume. Operator can press four-direction key to change the volume. Pressing confirm key again to exit.

The functions of 4 keys on the front panel are described as follow:

A. PRINT: Operator can print the waveform of real time, abnormal and the Trend Information by pressing this key.

B. FREEZE: Operator can freeze the real time waveform by pressing this key, and can also dissolve the freezing waveform by pressing again.

C. STORE: Operator can store the real time waveform to memory manually.

D. PRESS: Operator can start the Manual NIBP Monitoring by pressing this key, and one more press will terminate the NIBP monitoring immediately.

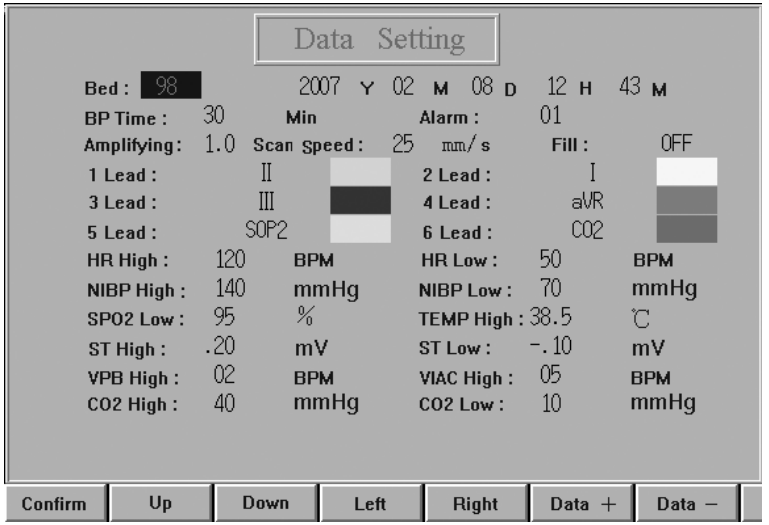
Operator can select each menu by pressing four-direction key.

Operator can also confirm the selection by pressing confirm key.

§5.1 Data Setting

Selecting the secondary menu Data Setting in the Main menu can enter the menu showed as follow. Operator can modify the date setting, selection of waveform and colour showed in each Lead, times of amplifying, speed of scaning, automatic NIBP timing and alarm setting.

The manufacturer default setting of parameters is showed as follow:



Pic 8

§5.1.1 Steps of Data Setting

A. Pressing four-direction key to make the cursor to the option and press confirm key to confirm the selection. Then the option will turn glittering which means this option is in the state of setup.

B. Pressing four-direction key again to increase or decrease the data of this option and

press the confirm key again when the data is desirable. Then the option will stop glittering.

C. Selecting the return option showed in the main menu in the bottom of screen can return to the monitoring state.

§5.1.2 Setting Bed Number and Date

Setting the date and bed number.

§5.1.3 Setting the timing of automatic NIBP monitoring

The timing of NIBP monitoring ranged from 1 minute to 240 minute, and operator can terminate automatic NIBP monitoring by setting timing of 00 minute.

§5.1.4 Select the ECG waveform and other waveform in each Lead

Operator can set each Lead for displaying different waveform. Except Lead No.1 must display the ECG Electrode Lead Ⅱ, other Lead can choose the Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V Electrode Lead of ECG or the waveform of Blood pressure, SpO2 and Respiration. Operator can choose the colour and painting of each Lead.

§5.1.5 Setting the scale of amplifying

Each ECG Electrode Lead can be amplified to 0.5, 0.75, 1.0, 1.5, 2.0 and auto, operator should select a proper scale to ensure the waveform of ECG is suitable.

§5.1.6 Setting the speed of scanning

Operator can set the ECG scanning speed to 12.5 ㎜/s, 25 ㎜/s or 50 ㎜/s.

§5.1.7 Alarm Setting

There are 3 level of alarm setting

Level 1: Alarm for the abnormity of Heart Rate(Tachycardia and Bradycardia) and NIBP.

Level 2: Alarm for the abnormity of Heart Rate(Tachycardia and Bradycardia), NIBP, SpO2 and ST Segment(ST Elevation and ST Depression).

Level 3: Alarm for the abnormity of Heart Rate(Tachycardia and Bradycardia), NIBP, Temperature, SpO2, ST Segment(ST Elevation and ST Depression), VPC, Bigeminal

rhythm, Tirgeminal rhythm, RonT, VTAC, Escape Beat, Sinus arrest and Lost lead.

§5.1.8 Range of Alarm Setting

Operator can set the upper limit and lower limit of normal parameter as follows:

A. Upper limit and lower limit of Heart Rate

B. Upper limit and lower limit of NIBP

C. Upper limit of Temperature

D. Lower limit of SpO2

E. Upper limit and lower limit of ST Segment

F. Upper limit of VPC

G. Upper limit of RonT

H. Upper limit of VTAC

Operator could change settings for different patient. The detail description of each Alarm Setting is as follows:

A. Alarm for the overstepping of the upper limit and lower limit of Heart Rate

The workable range of Heart Rate measure and alarm is 30～250 times/min.

The initial alarm setting is upper limit as 120 times/min, lower limit as 30 times/min.

B. Alarm for the overstepping of the upper limit and lower limit of NIBP

The workable range of NIBP measure is 10mmHg～280mmHg.

The workable range of NIBP alarm is 50mmHg～250mmHg and the alarm is available according to the systolic pressure’s change.

The initial alarm setting is upper limit as 140mmHg, lower limit as 75mmHg.

C. Alarm for the overstepping of the upper limit of Temperature

The workable range of Temperature measure is 32℃～43℃ and the result of temperature measurement may be changed according to the position of temperature probe in different part of body.

The workable range of Temperature alarm is 32℃～43℃.

The initial alarm setting is upper limit as 38℃.

D. Alarm for the overstepping of the lower limit of SpO2

The workable range of SpO2 measure is 40%～99%.

The workable range of SpO2 alarm is 50～99%.

The initial alarm setting is lower limit as 95%.

E. Alarm for the overstepping of the upper limit and lower limit of ST Segment

The unit of ST Segment is mv, and 0.1mv correspond to 1mm.

The workable range of ST Segment alarm is ±0.5mv.

The initial alarm setting is upper limit as +0.2mv, lower limit as –0.1mv.

F. Alarm for the overstepping of the upper limit of VPC

The unit of VPC is times/min.

The workable range of VPC alarm is 1～50 times/min.

The initial alarm setting is upper limit as 1 time/min.

G. Alarm for the overstepping of the upper limit of RonT

The workable range of RonT alarm is 1～5times.

The initial alarm setting is upper limit as 1 time.

H. Alarm for the overstepping of the upper limit of VTAC.

Description of VTAC: 3 VPB sequently happen.

The workable range of RonT alarm is 3～50times.

The initial alarm setting is upper limit as 3 times.

I. Alarm for the Escape Beat.

Description of Escape Beat: No QRS complex in 2 normal R-R interval.

J. Alarm for the Sinus arrest

Description of Sinus arrest: Longer than 2 seconds with no QRS complex.

K. Alarm for the lost lead.

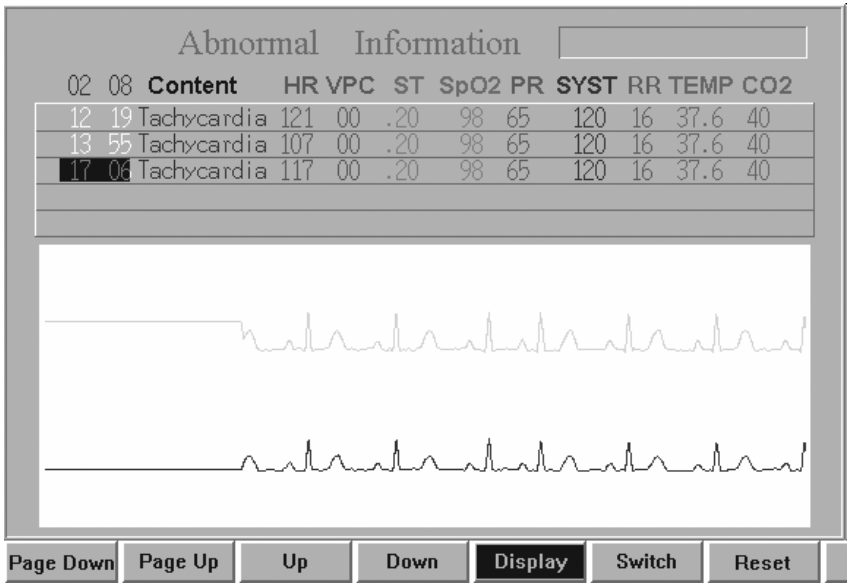
Description of lost lead : After 10 seconds of electrode lead loose or too much noise preventing analysis, the alarm will sound.

The alarm will work when one or more problems happen. Message will be displayed in the screen to indicate the kind of alarm and sound will remind the operator. Sound alarm will end after 1 minute, but the message will still hold on. If the alarm problem continues, the sound alarm will work again after 10 minutes. The next alarm problem will replace the message of previous one displayed in screen. The sound and message alarm could be terminated only when all the alarm problem is resolved.

§5.2 Abnormal Information

During the monitoring, equipment can automatically store abnormal data.

The menu of Abnormal Information is showed as Pic No.9.


Abnormal Information
02 08 Content HR VPC ST SpO2 PR SYST RR TEMP CO2
12 19 Tachycardia 121 00 .20 98 65 120 16 37.6 40
13 55 Tachycardia 107 00 .20 98 65 120 16 37.6 40
17 06 Tachycardia 117 00 .20 98 65 120 16 37.6 40
Page Down
Page Up
Up
Down
Display
Switch
Reset

Pic 9

This equipment can detect 10 kinds of abnormal ECG signal. The limit of each abnormal ECG signal can be modified in §5.2 Data Setting. Monitor will automatically store abnormal data according to the limit setted in the Data Setting. If there are sequent abnormal waveforms occurred, equipment will store the similar waveform by every 10 minute.

This monitor can distinguish Arrhythmia Alarms of Tachycardia, Bradycardia, VPB, SVPB, VTAC, RonT, Escape beat, Sinus arrest, bigeminy and trigeminy.

Memory can store 64 waveforms of ECG abnormity. Each waveform of ECG abnormity marks the happening time cause, and the waveforms of ECG abnormity is showed by index of table convenient for reviewing. If the memory is full filled, the new coming waveform of ECG abnormity will replace the earliest one. Equipment will store each waveform of ECG abnormity for 10 seconds and only the Lead No.1 waveform can be stored. The abnormity normally occur in the 7th second of each stored waveform.

Operator can review each waveform by selecting the option showed in the bottom of screen. Equipment also store the data of Heart Rate, VPC, ST Segment, SpO2, Pulse Rate, Blood pressure and the Temperature when the abnormal ECG waveform stored.

Operator can also print the abnormal waveform by press print key.

§5.2.1 Menu of Abnormal Information

In the state of Abnormal Information, operator can see several keys in the bottom of the screen as showed in Pic No.9.

The functions of the keys are described as follow:

A. Page Up and Page Down keys are used to let operator scan the Abnormal Data

B. Up and Down keys are used to let operator select the option

C. Display Waveform and Next Waveform keys are used to show stored waveform.

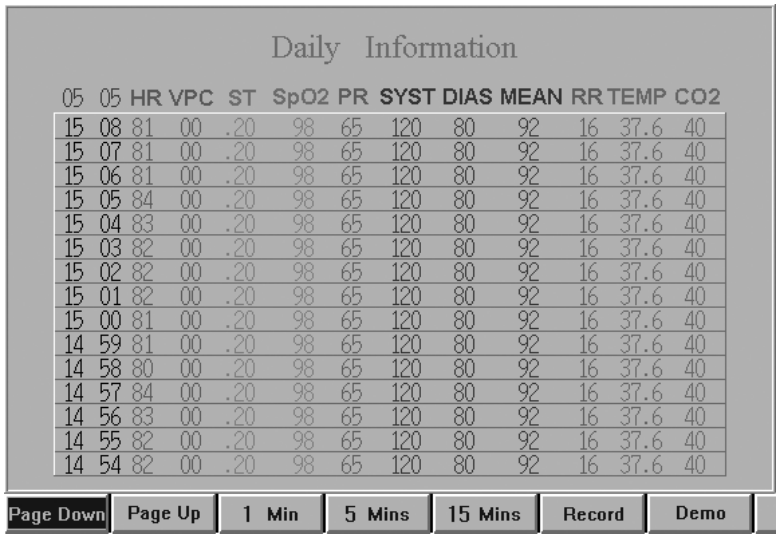
D. Reset key used to clean the stored data if the equipment monitor a new patient. Please be cautions that if operator select this key, all the Abnormal Data, Daily Data, Trend Information and Range of Alarm Setting are recovered to the initial state.

E. Switch key used to switch the ECG Waveform No.1 and ECG Waveform No.3.

F. Return key used to return to the monitoring state.

§5.2.2 **Daily Information**

Monitor can display 96 hours' Daily Data by every minute. The Daily Data contain the Date, Time, HR(Heart Rate), VPC, ST Segment, SpO2, PR(Pulse Rate), SYST(systolic pressure), DIAS(diastolic pressure), MEAN(mean arterial pressure), RR(Respiration Rate) and TEMP(Temperature). They are showed in Pic No.10.



Pic 10

Operator can print the daily information by press print key.

§5.3.1 Menu of Daily Information

In the state of Daily Information, operator can see several keys in the bottom of the screen as showed in Pic No.10.

The functions of the keys are described as follow:

A. Page Up and Page Down Keys are used to scan the Daily Data.

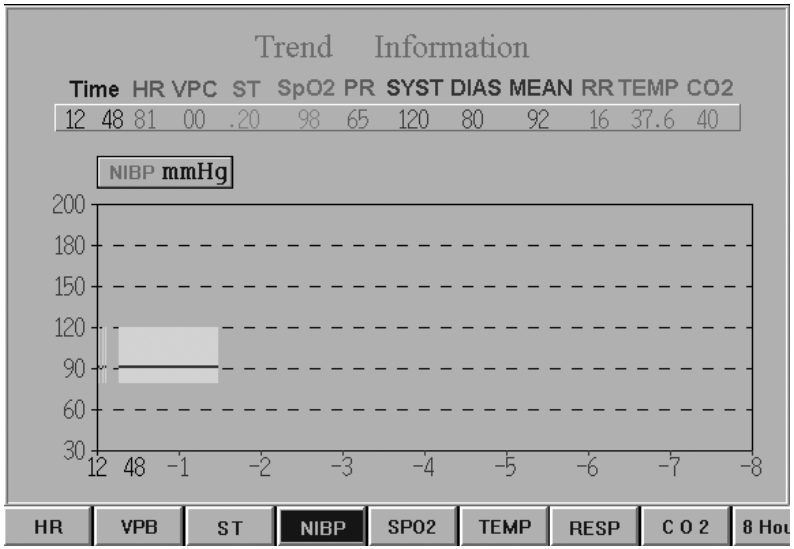
B. 1 Min, 5Min, 15Min Keys are used to fast scan the Daily Data.

C. Demo Key is used to display Demo Waveform. Press this key again can terminate the Demo State.

D. Return Key is used to return the monitoring state.

§5.4 **Trend Information**

Seven kinds of monitoring data(Heart Rate, NIBP, SpO2, Temperature, ST Segment, VPC and Respiration Rate) can be showed in the state of Trend Information. The demo chart of NIBP is showed in the Pic No.11. The ordinate means the value of blood pressure; the abscissa means the time. The Chart can present daily data by ways of 6 hours, 24 hours and 96 hours.



Pic 11

§5.4.1 Menu of Trend Information

In the state of Chart of Daily Data, operator can see several keys in the bottom of the screen as showed in Pic No.11.

The functions of the keys are described as follow:

A. Heart Rate, NIBP, SpO2, Temperature, ST Segment, VPC and Respiration Rate keys are used to display relevant chart.

B. 6 hours, 24 hours and 96 hours keys are used to show chart by different interval.

C. Return key is used to return the monitoring state.

§5.5 Alarm mute

When this option is selected, the alarm function of sound reminding is terminated and when the key is pressed again the function is restarted. When the alarm is mute, the mark of " " will show on the top-right of screen. When the alarm sound is available, the mark of " " will show on the top-right of screen. The classification of alarm is described in §5.1.7 and §5.1.8

§5.6 Filter

When this option is selected, the filter function is available and when the key is pressed again the function is terminated. Filter function is used to reduce the disturbance of AC signal which hinder the ECG signal. The mark of "Filter" will show on the top of the screen when the function is open.

§5.7 Automatic NIBP

Select this option start the Automatic NIBP function and press again terminate the function. Selecting this option is the same as pressing the "BP AUTO" key on the front panel. When the timing is 0, the NIBP measurement will start automatically. The detail setup of Automatic NIBP is described in §5.1.3 and §4.3.3.

§5.8 Help

Operator can read the E-document of Help stored in the equipment by selecting this option. The E-document shows the detail instruction of all the operation which convenient for the operator. Operator can read the instruction by page, chapter or Auto Scan. Select return key to return monitoring state.

§5.9 Print

Real Time Print: The displaying waveform in the Lead No.1 and No.3 is printed by press the "PRINT" key on the front panel.

Abnormal waveform Print: The abnormal waveform in the Lead No.1 and No.3 stored in memory is printed by press the "PRINT" key on the front panel.

Operator should enter the Abnormal Information menu first, then select the option of "Display Waveform". After the abnormal waveform is showed, operator can press the "PRINT" key and print the abnormal waveform.

Chart of Daily Date Print: The Chart of Daily Date Print is printed by press the "PRINT" key on the front panel.

Operator should enter the Chart of Daily Date menu first, then select the different option such as Heart Rate, NIBP, SpO2, Temperature, ST Segment, VPC and Respiration Rate. After the chart is showed, operator can press the "PRINT" key and print the relevant chart.

If the printer does not work after Operator presses the "PRINT" key, some situation should be considered: whether the print paper is used out; whether the cover of printer is closed correctly.

Please rip the printed paper upward to avoid locking paper.

Section 6 *Features and Technical Specifications*

Safety: Accord with Standard GB9706.25 and GB9706.1

Resist electric shock: Class I Class CF

Apply to: Adult, Child, Baby

Size of Screen: 6″ TFT Colour LCD

Resolution: 640*480

Display Waveform: 4 Leads Display waveforms of ECG, Respiration, NIBP and SpO2

Colours of Waveform: 15 Kinds

Freeze Waveform: Available

Monitor Functions: Heart Rate, VPC, Three Level ST Segment, NIBP, SpO2, Pulse Rate, Respiration Rate and Temperature.

§6.1 ECG

Input: 5 Electrode Leads RA, LA, RL, LL, C (V1～V6)

Electrode Lead: Standard Ⅰ, Ⅱ, Ⅲ; Body Electrode Lead aVR, aVL, aVF; Bosom Electrode Lead V1～V6

Time of Signal Amplifying: 0.5, 0.75, 1.0, 1.5, 2.0

Range of ECG Measurement: 30 times/min～250 times/min

Precision of ECG: ±5%

Scan Speed: 12.5mm/s, 25mm/s, 50mm/s

Real Time ECG Analyse and Review: Available

Range of Alarm: 30 times/min～250times/min

Mode of Alarm: Sound and Screen Remind Alarm, can review

Work with electrosurgical unit: Available

Work with de-trembling: Class CF

Sustain 4000VAC/50Hz electric shock

§6.2 NIBP

Measure Method: Advanced One-step Method with Automatic / Manual Measurement

Measure Unit: mmHg and kPa

Measure parameter: SYST(systolic pressure), DIAS(diastolic pressure), MEAN(mean arterial pressure)

Measure Range: 10mmHg～280mmHg； 1.3kPa～37kPa

Precision of NIBP: ±5mmHg;±0.7kPa

Protection of Over Pressure: ＜330mmHg；＜44.0kPa

Alarm: SYST, DIAS, MEAN

§6.3 SpO2

Range of SpO2 Measurement: 40%～99%

Precision of SpO2: Within 85%～99%:±2% ; Within 60%～85%:±4%

Alarm Range: 0～99%

Measure Pulse Rate Range: 30 Times/min～200 Times/min

Precision of Pulse Measurement: ±5%

§6.4 Temperature

Measure Range: 32℃～43℃

Precision of Temperature Measurement: ±0.3℃

§6.5 Respiration

Measure Range: 4 Times/min～120 Times/min

Precision of Respiration Measurement: ±2 Times/min

§6.6 Waveform Display

Waveform Display: Display 4 Waveform in screen.

Trend Information: Store 96 hours chart of data of Heart Rate, NIBP, SpO2, Temperature, Respiration, VPC and ST Segment.

Store ECG Waveform: Store 64 waveforms of ECG by every 10 seconds. Can freeze the waveform.

§6.7 Alarm

Message for the abnormal system alarm of lost lead or too much noise.

Message for the abnormal data alarm of Heart Rate(Tachycardia and Bradycardia), NIBP, Temperature, SpO2, ST Segment(ST Elevation and ST Depression), VPC, Bigeminal rhythm, Tirgeminal rhythm, RonT, VTAC, Escape Beat and Sinus arrest.

Ways of Alarm: Sound and message in the screen.

Alarm Level: 3 levels

§6.8 Print(Optional)

Real Time Print: 2 Leads ECG waveform and the data of Heart Rate, NIBP, SpO2, Temperature, Respiration, Pulse Rate and ST Segment is real time printed.

Abnormal Print: 2 Leads abnormal ECG waveform and he data of Heart Rate, NIBP, SpO2, Temperature, Respiration, Pulse Rate and ST Segment is printed

Trend Information Print: The Chart of Heart Rate, NIBP, SpO2, Temperature, Respiration, VPC and ST Segment is printed.

Section 7 *Error Messages and Troubleshooting*

Cautions:Operator should not open the equipment except manufacturer.

Sort	Problem	Cause	Solutions
ECG	No ECG Waveform (Only one line)	Electrode is not positioned correctly	Check the position of electrodes, especially check the place of electrode lead Ⅱ. The detail position and colour of electrode lead is shown in §4.1.1 Selection of Electrode Lead.
	Noise	Electrode is not positioned correctly Patient's skin is not cleaned completely.	A. See the instruction of positioning the electrode. B. Check whether the electrode is dry. C. Check whether the alcohol react with the mucus on the electrode.

	(Waveform is disorder)	Patient's disturbance	A. If patient wear chemical fibre underclothes in dry weather, please check whether these clothes will cause disturbance. Operator could use cotton-made towel or gauze to separate the skin and clothes if necessary. B. In summer, sweat may cause the electrode floating. Please check and press the electrode to avoid disturbance. C. If the situation continues, please replace the electrode.
		Electromagnetism field disturbance	A. Operator should take some steps to restrain or keep away from the source of electromagnetism field. B. Open filter function. C. Do not use one electrical outlet with this equipment and electrosurgical unit.
NIBP	Error result or no result	Leaking air。	A. Check the NIBP cuff whether it is in good condition or replace the NIBP cuff. B. Check the socket of NIBP cuff connecting to the equipment.
		Wrong usage of NIBP cuff	A. Please check the NIBP cuff and colligate it again every 8 hours. B. The NIBP cuff should at the same level with heart.
		Wrong Size of NIBP cuff	A. Check the NIBP cuff whether it is suit for adult child or baby.

		Patient movement	A. The patient should be silent during the course of measuring.
SpO2	Error result or no result	Wrong usage of probe	A. Please make sure the root segment of nail of forefinger is just facing the position of the clamp where is emitting the red light. B. Please do not put SpO2 probe to the limb where is used for NIBP monitoring.
		Patient movement	A. The patient should be quiet during the course of measuring.
		Too strong light	A. Avoid the light irradiate the probe directly.
		Haemoglobin function defect	A.Take steps to avoid haemoglobin function defect.
Temperature	No result	Lost of the probe	A. Check the probe.
Respiration	No result	Wrong place of electrode or wrong selection of electrode lead	A. Check the selection of electrode lead and the place of electrode.
Battery	White display in screen Indicator light not work or extinguished after 10s	Battery is exhausted	A. Connect the equipment to AC Power and recharge the battery for 10 minute.

Power	No display Indicator light not work or extinguished after 10s	no power in electrical outlet	A. Check the electrical outlet whether it is with 220V Power.
Printer	Not work	Locking paper or no paper.	A. Rip the printed paper upward to avoid locking paper. B. Close the cover of printer in right step. C. Replace the print paper and make sure the side of hot-sensitive face to up.

Table 5

Section 8 *Maintenance*

§8.1 Cleaning and Disinfecting

A. Clean equipment after use

Please turn off the equipment and cut off the Power before cleaning. Then clean the surface of the monitor with a soft cloth moistened with neutral soap, water or alcohol(>70%), and wipe with a dry cloth or gauze. Operator should notice that only dry cloth or gauze can be used to wipe the screen. Remove dust from the vent holes on the panels with a cotton swab.

B. Clean and disinfect accessories(Electrode Lead and Probe)

Clean the accessories after use every time with a soft cloth moistened with neutral soap, water or alcohol(>70%), and wipe with a dry cloth or gauze.

Disinfect the accessories with a non-abrasive cloth moistened with disinfectant and use appropriate concentration.

C. Clean and disinfect accessories(NIBP cuff)

Please take out rubber in the NIBP cuff carefully. Then clean the cloth-coat with neutral soap.

Please clean the surface of rubber in the NIBP cuff and the air hose with a soft cloth moistened with alcohol(>70%). Then dry them sufficiently.

Avoid use ultraviolet radiation, ozone or high pressure disinfection to the rubber and air hose.

Avoid water flow into the inside of the air hose. Operator should avoid the air hose dipping in the water, otherwise the remain water may cause inaccuracy of NIBP measurement seriously.

D. Disposing of used accessories

Please dispose the used accessories follow the rule of disposing medical castoff made by the local government.

E. Disinfecting of the equipment

Monitor could be disinfected by ultraviolet radiation disinfection by 30 minutes.

§8.2 Maintenance

Please maintain the equipment periodically to keep your monitor in optimum condition.

§8.2.1 Inspection before/after Use

Please check the following items before turning on the power of the equipment:

Check the probe lead and sensor whether they are lost or the NIBP cuff and air hose are leaking air.

Check the electrical outlet and Power cord whether they are in good condition.

Keep all the keys, switches and sockets in good condition.

Check the settings whether is correct.

Please check the following items after every use:

Clean and disinfect the probe and lead after every use.

Position the equipment to the place where is dry and clean.

§8.2.2 Yearly Inspection

Please check the following items every year periodically:

Monitor is not dirty, damaged or rusty.

No key or switch is broken.

No damage to the socket of the monitor.

Power cord is not damaged.

Screen is clean.

Screen display is correct.

Clock is correct.

Settings are correct.

The specified electrodes, sensors and probes are used.

Printer module operates properly when used.

The recorded data are correct.

No current leakage.

Supplied voltage is correct

Measurement accuracy is within the specified range.

§8.2.3 Period Inspection

Please check and verify the monitor every year by professional operator to make sure the safety and accuracy of measurement of the equipment.

Section 9 *Package Transportation and Storage*

§9.1 Package

§9.1.1 Monitor is packed with paper-made container, plastic foam and plastic bag.

§9.1.2 Your can find the certification of checkout, user manual and list in container.

§9.1.3 Conditions for transportation and storage:

Environment Temperature: －10℃～40℃

Range of Relative Humidity: ＜95％

Range of Atmospheric Pressure: 50.0 Kpa～106.0 Kpa

§9.1.4 Indication on package for transportation and storage:

Upwards Should not inverse the package.

Keep Dry Please store the package in dry environment.

Be Careful Please carefully transport the package.

§9.1.5 Size and weight of package:

Size: 260×210×200 Weight: 2Kg

§9.2 Transportation

Carefully transport the package by truck, train or airplane and avoid rain pouring and sun irradiation.

§9.3 Storage

Store the packed monitor in clean, dry and well ventilated room.